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IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

NORTH AMERICAN VACCINE, INC. and
NATIONAL RESEARCH COUNCIL OF CANADA,
Petitioners,

v.

AMERICAN CYANAMID COMPANY and
PRAXIS BIOLOGICS, INC.,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Did the U.S. Court of Appeals for the Federal Circuit exceed its reviewing jurisdiction by invoking the harmless error doctrine on the basis of its independent determination of the fact-based meaning of technical terms in a patent claim, after holding that the District Court's findings related to that issue were infected with error?

PARTIES

The National Research Council of Canada is an agency corporation of Canada, wholly owned by Her Majesty the Queen in Right of Canada, reporting to Parliament through the Minister of Industry, Science and Technology. The parent companies, subsidiaries (except wholly-owned subsidiaries), and affiliates that have issued shares to the public, of North American Vaccine, Inc. are IVAX Corporation and BioChem Pharma, Inc.

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OPINIONS OF OTHER COURTS

The petitioner commenced this action in the U.S. District Court for the Southern District of New York. The Court's oral findings of fact and conclusions of law (App. at 28a-44a) are reported at 24 U.S.P.Q.2d 1898 (S.D.N.Y. 1992).

The majority (App. at 1a-17a) and dissenting (App. at 18a-26a) opinions of the U.S. Court of Appeals for the Federal Circuit, which affirm in part and reverse in part the District Court's judgment, are reported at 7 F.3d 1571 (Fed. Cir. 1993).

The Court of Appeals' order denying the petitioners' petition for rehearing and suggestion of rehearing in banc (App. at 45a-46a) is unreported.

JURISDICTION

The judgment of the U.S. Court of Appeals for the Federal Circuit was entered on October 6, 1993.

On October 27, 1993, the petitioners filed a timely petition for rehearing and suggestion of rehearing in banc, which the Court denied on December 8, 1993.

This Court has jurisdiction to review the judgment of the Court of Appeals under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED IN THE CASE

1. 28 U.S.C. § 2111 provides:

> § 2111. Harmless error
>
> On the hearing of any appeal or writ of certiorari in any case, the court shall give judgment after an examination of the record without regard to errors or defects which do not affect the substantial rights of the parties.

2. Rule 52(a) of the Federal Rules of Civil Procedure provides:

> Rule 52. Findings by the Court; Judgment on Partial Findings
>
> (a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. *Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly er-*

> *roneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses.* The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. It will be sufficient if the findings of fact and conclusions of law are stated orally and recorded in open court following the close of the evidence or appear in an opinion or memorandum of decision filed by the court. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rule 12 or 56 or any other motion except as provided in subdivision (c) of this rule.

(Emphasis supplied.)

STATEMENT OF THE CASE

Introduction

This case involves the standard of review applied by the U.S. Court of Appeals for the Federal Circuit in determining that a patent held by the petitioners was not infringed. It raises an important question of the proper relationship between the Federal Circuit and the U.S. District Courts in deciding patent cases.

In the decision from which the petitioners seek a writ of certiorari, a panel of the Federal Circuit held that the District Court's decision was based on error, but nevertheless affirmed that decision under the harmless error doctrine by independently deciding factual questions based in part on selected trial testimony, in violation of Rule 52(a) of the Federal Rules of Civil Procedure. In so doing, the Federal Circuit undermined the District Court's role as fact finder to determine the credibility of witnesses.

The Petitioners' Patent

The petitioners are the owner and licensee of U.S. Patent No. 4,356,170 ("the patent"), issued to Harold J. Jennings and Czeslaw Lugowski. The technology em-

braced by the patent involves vaccines against bacterial infections such as meningitis, which can have devastating effects on young children. These vaccines employ "polysaccharides," which are components of bacteria that stimulate the human immune system to make antibodies. The patented invention is a vaccine made from "conjugates" (which are simply molecules chemically joined together), in which a protein is linked to a "terminal portion" or end of the polysaccharide.

The Respondents' Accused Product

The respondents' product accused of infringement is an infant meningitis vaccine called HibTITER. HibTITER is based upon a species of polysaccharide expressly recited in the asserted claims of the patent. The HibTITER vaccine contains some polysaccharides having a protein linked to only one terminal portion and others having proteins linked to both terminal portions.

The District Court Decision

Pursuant to 28 U.S.C. § 1338(a), the petitioners commenced this action in the U.S. District Court for the Southern District of New York, charging the respondents with infringement of the patent by the manufacture and sale of HibTITER. At trial, the parties presented "a substantial amount of testimony and documents received into evidence bearing on the question of interpretation" of the claims at issue. App. at 35a; 24 U.S.P.Q.2d at 1901.

Immediately following the parties' closing statements, the Court delivered oral findings of fact and conclusions of law. The Court stated: "I think the case is a close one" and "the scales tip, not drastically, but I think they tip in favor of the defense." App. at 29a; 24 U.S.P.Q.2d at 1898. The District Court found the pertinent claims of the patent invalid (a holding reversed by the Court of Appeals). The District Court, however, also made findings on the issue of infringement.

In its infringement analysis, the District Court was required to determine whether the phrase "linked . . . to a terminal portion of the polysaccharide" encompasses conjugates having proteins at both ends of the polysaccharide and not just one. Obviously, a conjugate having a protein at both ends can be said to be in the category of conjugates having a protein at an end. After concluding that the language, by itself, could be read either way, the Court proceeded to consider extrinsic evidence, including an article and a speech by Jennings, one of the inventors, concerning his research.

Based on a detailed analyses of the extrinsic evidence, the District Court held that the claims of the patent were limited to conjugates with a protein linked to only one terminal portion. In so holding, the Court stated that "the basic reason why I am holding in favor of the defendants on the question of interpretation" is that the patent did not clearly express "in the English language" either the inventor's intention "to broaden his patent beyond what was contained in the article and the speech" or his intention "to depart from the objectives that he so clearly had in his experimentation described in his article and his speech." App. at 39a; 24 U.S.P.Q.2d at 1902.

The Appeal

On appeal, a panel of the Federal Circuit unanimously reversed the District Court's holding of invalidity, but affirmed its holding of noninfringement by a divided vote.

In its opinion, the Court specifically rejected the District Court's reliance on Jennings' article and speech, stating that "[t]here is no inconsistency between writing a paper (or giving a speech) on a particular embodiment of an invention and then claiming one's invention more broadly in a patent application." App. at 13a; 7 F.3d at 1578. Thus, the Federal Circuit clearly held that the District Court had made a major error by concluding "that the narrow scope of the article limits the scope of the

patent claims, which should be judged on their own merits." *Id.*

Notwithstanding the closeness of the case and the District Court's improper reliance on the article and speech, the Federal Circuit did not remand the case to the District Court for reconsideration of the infringement issue on a proper standard and relevant evidence. Instead, a majority of the Federal Circuit panel found the District Court's error to be harmless by making its own independent *de novo* factual determinations in light of selected evidence in the record.

In dissent, Circuit Judge Rader stated:

> The panel's opinion correctly notes the trial court's error in relying extensively on the inventors' scientific articles for its claim interpretation. The trial court referred to the scientific writings as "the most important point in the evidence." Surprisingly, however, the panel's opinion did not consider this error a cause for reversal. In a case the district court repeatedly characterized as "very close," this extensive reliance on impermissible evidence constitutes reversible error. Without the primary source of evidence upon which the district court based its decision, this "very close" case would no doubt have ended differently.

App. at 18a; 7 F.3d at 1580 (Rader, J., dissenting).

REASONS FOR GRANTING THE WRIT

The U.S. Court of Appeals for the Federal Circuit has exclusive jurisdiction over appeals from all U.S. District Courts in patent cases. Because of this unique nationwide jurisdiction, this Court has stated that the Federal Circuit's appellate role is "a matter of special importance to the entire Nation." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 113 S. Ct. 1967, 1971 (1993).

The Federal Circuit has from time to time rendered decisions that have been criticized, even by judges of the Court itself, as usurping the fact-finding role of the Dis-

trict Courts. *See, e.g., Malta* v. *Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1331 (Fed. Cir. 1991) (Newman, J., dissenting) (criticizing the majority for rejecting a jury verdict and making a *de novo* determination of the factual issue of infringement), *cert. denied*, 112 S. Ct. 2942 (1992).

This Court has previously considered—and limited—the role of the Federal Circuit in reviewing questions of fact underlying the issue of patent validity. *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809 (1986). Although patent validity ultimately is a question of law, it necessarily involves several basic factual questions. *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966).

In *Dennison*, the Federal Circuit reversed a District Court finding of patent invalidity without referring to Rule 52(a) of the Federal Rules of Civil Procedure or explaining why the District Court was "clearly erroneous" under the Rule 52(a) standard of review of factual questions. Bereft of an opinion of the Federal Circuit on the complex relationship between the factual issues and the ultimate determination of validity, this Court summarily vacated the judgment of the Court of Appeals and remanded the case for further consideration in light of Rule 52(a).

The present case concerns the role of the Federal Circuit in reviewing questions of fact underlying the issue of patent *infringement* and raises a similar issue. It is imperative that the Federal Circuit review patent infringement decisions, as well as decisions on validity, in a manner consistent with Rule 52(a). As set forth below, however, the panel majority in this case made two related errors, each of which intruded upon the assigned role of the District Court to find the facts.

Like the issue raised in *Dennison*, the issue of judicial administration raised in this petition is of significant importance to the Federal Circuit's review of decisions in patent cases nationwide. Review by this Court is there-

fore warranted, not on the substantive patent issues which the Court need not address, but on the proper allocation of functions between the Federal Circuit and the District Courts.

I. THE FEDERAL CIRCUIT ERRED IN RELYING UPON THE HARMLESS ERROR DOCTRINE TO AFFIRM A FINDING OF NONINFRINGEMENT AFTER REJECTING THE "BASIC REASON" FOR THE DISTRICT COURT'S DECISION

Under the harmless error doctrine of 28 U.S.C. § 2111, a Court of Appeals need not reverse a decision of a District Court based on errors that "do not affect the substantial rights of the parties." This Court has articulated the following standard to be used in determining whether an error is harmless:

> [I]f one cannot say, with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error, it is impossible to conclude that substantial rights were not affected. The inquiry cannot be merely whether there was enough to support the result, apart from the phase affected by the error. It is rather, even so, *whether the error itself had substantial influence*.

Kotteakos v. *United States*, 328 U.S. 750, 765 (1946) (interpreting old 28 U.S.C. § 391) (emphasis supplied).

Here, it is clear from the District Court's opinion itself that the error was not harmless. The District Court stated that "the case is a close one," App. at 29a; 24 U.S.P.Q.2d at 1898, and identified the article and speech as "*the basic reason* why I am holding in favor of the defendants on the question of interpretation." App. at 39a; 24 U.S.P.Q.2d at 1902 (emphasis supplied). It cited the nature of Jennings' research, as described in the article and speech, as "[p]erhaps *the most important point* in the evidence." App. at 35a; 24 U.S.P.Q.2d at 1901 (emphasis supplied).

When the majority of the Federal Circuit panel held that reliance on this evidence was impermissible, however, it did not address whether the District Court's reliance on this evidence had a "substantial influence" on its decision within the meaning of *Kotteakos* and 28 U.S.C. § 2111. Had it done so, it would have had to agree with the dissenting judge that "[w]ithout *the primary source of evidence upon which the district court based its decision*, this 'very close' case would no doubt have ended differently." App. at 18a; 7 F.3d at 1580 (Rader, J., dissenting) (emphasis supplied).

II. THE PANEL MAJORITY ALSO ERRED BY DECIDING FACTUAL QUESTIONS IN INTERPRETING THE CLAIMS OF THE PATENT

The majority of the Federal Circuit panel held that the District Court's reliance on Jennings' article and speech was harmless error by improperly determining questions of fact confided to the District Court. Determination of patent infringement requires interpretation of the scope and meaning of a patent's claims and application of the properly construed claims to the allegedly infringing product. The first of these questions is ultimately a question of law, and the second is a question of fact. *E.g., Winas* v. *Denmead*, 56 U.S. (15 How.) 330, 338 (1853).

Even though patent claim interpretation is a question of law, as here it often involves underlying questions of fact, like the question of patent validity addressed in *Dennison*. Over 100 years ago, this Court held:

> Where the specification and claim, both in the original and reissued patents, are expressed in ordinary language, without employing any technical terms or terms of art, the question whether the reissued patent is for the same invention as that described in the original patent or for a different one is purely a question of construction, but where both or either contain *technical terms or terms of art* the court may hear

> the testimony of scientific witnesses to aid the court in coming to a correct conclusion. Cases doubtless arise where the language of the specification and claim, both of the surrendered and reissued patents, is so interspersed with technical terms and terms of art that *the testimony of scientific witnesses is indispensable to a correct understanding of its meaning.* Both parties in such a case would have a right to examine such witnesses, and it would undoubtedly be error in the court to reject the testimony . . . .

Seymour v. *Osborne*, 78 U.S. (11 Wall.) 516, 546 (1870) (emphasis supplied).

More recently, the Federal Circuit has recognized exactly this point:

> Claim interpretation is a question of law, *having factual underpinnings.* When the meaning of key terms of claims is disputed, as in this case, extrinsic evidence may be adduced including testimony of witnesses, and reference may be had to the specification, the prosecution history, prior art, and other claims.

Tandon Corp. v. *U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1021 (Fed. Cir. 1987) (affirming I.T.C. finding of noninfringement) (emphasis supplied).

Thus, the Federal Circuit has acknowledged the limitations on its role in reviewing matters of patent claim interpretation:

> Claim construction is reviewed as a matter of law. However, *interpretation of a claim may depend on evidentiary material about which there is a factual dispute, requiring resolution of factual issues as a basis for interpretation of the claim.* In this case, there was extensive testimony on the issue of claim construction, including the conflicting views of experts on both legal and factual questions. *Those factual considerations that are pertinent to the district court's construction of the term "bottomless" are reviewed under the clearly erroneous standard.*

H.H. Robertson, Co. v. *United Steel Deck, Inc.*, 820 F.2d 384, 389 (Fed. Cir. 1987) (affirming District Court finding of infringement) (citations omitted) (emphasis supplied).

But, as shown by the present case, that acknowledgment "keep[s] the word of promise to our ear [a]nd break[s] it to our hope," [1] unless the Federal Circuit is required to observe proper standards of review.

As held in this Court's *Dennison* decision, it is error for the Federal Circuit to decide questions of law involving underlying disputed facts without regard to the factual findings of the District Court and the "clearly erroneous" standard for reviewing those fact findings under Rule 52(a) of the Federal Rules of Civil Procedure. *Dennison*, 475 U.S. at 811.

The proper construction of the patent claims at issue involves the interplay between the phrase "linked . . . to a terminal portion of the polysaccharide" and the recitation in the claims of a specific species of bacterium (*Haemophilus influenza*) as understood by one skilled in the art in light of the patent specification.

The panel majority, instead of remanding to the District Court to make findings based upon the evidence properly before it, independently determined factual questions without the benefit of having sat through three weeks of trial and hearing the testimony of ~~six~~ five scientific witnesses on the dispositive issues. This scientific testimony was "indispensable" to a correct understanding of the meaning of the claims under the teaching of *Seymour* v. *Osborne*, and it was for the District Court, not the reviewing court, to make the proper findings. But, after making findings as to what the specification did or did not teach, an inherently fact-based issue, the panel majority chose to credit the testimony of one of the respondents' expert wit-

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[1] William Shakespeare, *Macbeth*, act 5, sc. 7.

nesses, whom they never saw, and whose testimony contradicts a finding of the District Court. App. at 10a-11a; 7 F.3d at 1577. The District Court specifically stated that *it* would not rely upon the testimony of this witness in interpreting the patent and instructed counsel for the petitioner that he need not cross examine the witness regarding interpretation. Trial transcript of Aug. 20, 1992 at 1447.

In deciding how to reconcile the terms of the patent claims independently of the District Court, based on a selective reading of the evidence adduced at trial, the panel majority improperly decided the disputed facts underlying the interpretation of the patent claims.

III. THE FEDERAL CIRCUIT'S ERRORS EACH UNDERMINED THE FACT FINDING ROLE OF THE DISTRICT COURT

In this case, the majority's misapplication of the harmless error doctrine of 28 U.S.C. § 2111 undermined the role of the District Court to determine disputed facts by denying the District Court the opportunity to weigh only the evidence properly before it in reaching a decision. As the dissent recognized, given the closeness of the case, it is likely that the District Court would have reached a different decision if it had had this opportunity. The Federal Circuit made an even more direct assault on the fact-finding role of the District Courts, as set forth in Rule 52(a), by evaluating witness credibility and deciding factual questions for itself.

Preserving the proper fact finding role of the District Courts serves important public purposes:

> The rationale for deference to the original finder of fact is not limited to the superiority of the trial judge's position to make determinations of credibility. The trial judge's major role is the determination of fact, and with experience in fulfilling that role comes expertise. Duplication of the trial judge's efforts in the

> court of appeals would very likely contribute only negligibly to the accuracy of fact determination at a huge cost in diversion of judicial resources.

Anderson v. *City of Bessemer City*, 470 U.S. 564, 574-75 (1985).

Especially given the unique nationwide appellate jurisdiction of the U.S. Court of Appeals for the Federal Circuit, it is important that this Court provide guidance and direction to prevent future usurpation of the District Courts' fact finding role in patent infringement cases. The present case affords the vehicle for doing so in a specialized but highly important area of the law, in which bench, bar and litigants all have a strong interest in knowing the procedural rules by which they must live.

CONCLUSION

For the foregoing reasons, petitioners respectfully request that this petition for a writ of certiorari be granted.

Respectfully submitted,

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APPENDIX

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

93-1076

NORTH AMERICAN VACCINE, INC. and
NATIONAL RESEARCH COUNCIL OF CANADA,
Plaintiffs-Appellants,

v.

AMERICAN CYANAMID COMPANY and
PRAXIS BIOLOGICS, INC.,
Defendants-Appellees.

Appealed from U.S. District Court
Southern District of New York

DECIDED: October 6, 1993

Before LOURIE, *Circuit Judge*, SKELTON, *Senior Circuit Judge*, and RADER, *Circuit Judge*.

LOURIE, *Circuit Judge*.

National Research Council of Canada and its exclusive licensee, North American Vaccine (collectively NRC), appeal from the judgment of the United States District Court for the Southern District of New York holding claims 12 and 25 of U.S. Patent 4,356,170 invalid for

indefiniteness under 35 U.S.C. § 112, ¶ 2 (1988), and not infringed by American Cyanamid Co. and Praxis Biologics, Inc. (collectively Cyanamid). *North American Vaccine, Inc. v. American Cyanamid Co.*, 24 USPQ2d 1898 (S.D.N.Y. 1992). We affirm-in-part and reverse-in-part.

BACKGROUND

On February 28, 1991, NRC brought an action against Cyanamid alleging infringement of the '170 patent. That patent, entitled "Immunogenic Polysaccharide-Protein Conjugates," relates to human infant vaccines against bacterial infections such as meningitis. The principal components of the vaccines are polysaccharide-protein conjugates. The polysaccharide, which is derived from the bacteria against which immunization is sought, has antigenic properties that elicit an immune response. Infant immune systems, however, do not respond well to the polysaccharide unless it is linked to a protein.

While linking of the polysaccharide and protein enhances infants' immune response to the antigenic polysaccharide, the immune response is hampered by "crosslinking." The parties indicate that crosslinking obstructs the antigenic sites of the polysaccharide, precluding an effective immune response. The amount of crosslinking increases with the number of proteins that are linked to the polysaccharide. The claimed invention purports to avoid the problem associated with crosslinking by linking the protein only to a terminal portion of the polysaccharide, thereby preserving the antigenic properties of the polysaccharide and producing an immune response in infants. The meaning of the expression "a terminal portion" in the claims is a key issue in this case. The meaning of the term "crosslinking" is also contested.

Trial was limited to the issues of infringement and validity of claims 12 and 25, which are directed, respectively, to a polysaccharide-protein conjugate and a human

infant vaccine comprising that conjugate. Both are dependent upon claim 11, which reads:

> 11. An antigenic-polysaccharide-protein conjugate wherein the polysaccharide and protein are covalently linked through a
>
> CH_2-NH-protein
>
> *linkage to a terminal portion of the polysaccharide without significant crosslinking*, said antigenic polysaccharide having a MW [molecular weight] above about 2,000.

(emphasis added). Claims 12 and 25 read as follows:

> 12. The conjugate of claim 11 wherein the antigenic polysaccharide is selected from the group derived from meningococci, *Haemophilus influenza*, pneumococci, beta-hemolytic streptococci, and E. coli.
>
> 25. A human infant vaccine comprising the conjugate of claim 11 wherein the polysaccharide comprises at least one of meningococcal polysaccharide and *Haemophilus influenza polysaccharide*.

(emphasis added).

A polysaccharide is a sugar molecule having a carbon backbone with hydroxy groups attached, to which proteins may be linked. Linking a protein to a polysaccharide generally involves modifying the hydroxy groups to create one or more active sites and covalently linking the activated polysaccharide to a free amino group of a protein. The result is a polysaccharide-protein conjugate.

Cyanamid's accused product, "HibTITER," is a vaccine against *Haemophilus influenza* (*H. flu*) type b (Hib) bacteria that can cause meningitis. HibTITER consists of Hib polysaccharides linked to one or more proteins. Specifically, it is comprised of three components referred to as "monomers," "dimers," and "trimers." Monomers,

which constitute 50% of the polysaccharide-protein molecules of HibTITER, consist of a single protein linked to a terminal end of one or more polysaccharides; dimers consist of two proteins linked together by polysaccharide; and trimers consist of three proteins linked together by polysaccharides. The protein linkage in each of these components is at a terminal portion of the Hib polysaccharide; none has a protein linkage along the backbone of the polysaccharide. Monomers, having a protein linkage at only one terminal, are referred to as monofunctional. Dimers and trimers, having linkages at both terminals of the polysaccharide, are referred to as difunctional and exhibit what has been called end-to-end cross-linking.

The district court entered judgment for Cyanamid, holding that claims 12 and 25 were not infringed and were invalid for indefiniteness under 35 U.S.C. § 112, second paragraph. NRC appeals from that judgment.

DISCUSSION

A. *Infringement*

A determination of patent infringement requires a two-step analysis. First, a claim must be interpreted to determine its proper scope and meaning; second, it must be determined whether an accused device is within the scope of the properly interpreted claim. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed. Cir. 1988). The first step is an issue of law and the second a question of fact. *Minnesota Mining & Mfg., Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1570, 24 USPQ2d 1321, 1330 (Fed. Cir. 1992) (citations omitted). A determination of literal infringement requires that each limitation in the asserted claims be present in the accused device. *Hi-Life Products., Inc. v. American Nat'l Water-Mattress Corp.*, 842 F.2d 323, 325, 6 USPQ2d 1132, 1133 (Fed. Cir. 1988). Only the issue of literal infringement is before us in this case.

Whether HibTITER, which includes monomers, dimers, and trimers, infringes claims 12 and 25, turns on our interpretation of the limitation "linkage to a terminal portion of the polysaccharide without significant crosslinking" in claim 11. It is not disputed that the monomer components in HibTITER meet this limitation. Thus, if, contrary to what the district court decided,[1] the monomers themselves meet all the other limitations of the claims, including being a conjugate, infringement of the claims would be established because they contain "linkage to a terminal portion of the polysaccharide without significant crosslinking" and they are quantitatively a significant component of the product. However, at oral argument, counsel for NRC stated that NRC is not contesting this aspect of the court's decision.[2] The only issue

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[1] The court rejected NRC's argument that infringement is established on the basis of the monomers alone. NRC had asserted that "conjugate" in claim 11 referred to an individual molecule and that HibTITER infringed since each monomer molecule was within the scope of the asserted claims.

[2] At oral argument, Judge Lourie asked counsel for NRC about the meaning of the word "conjugate" in the claims. Counsel for NRC responded:

> Well, the word "conjugate" was in dispute at trial, and my brother Mr. Dunner has made an issue of it on appeal, but it is really not an issue *because we are not contesting the district court's interpretation of the word conjugate.* The district court interpreted the word "conjugate" as embracing all the molecules in the mixture and therefore and [sic] the accused product really has three types of molecules. It has so-called monomers, which have no cross-linking, and it has dimers and trimers which have the end-to-end cross-linking. And we have an argument below that the monomers should infringe irrespective of the dimers and trimers. And the district court rejected that because he said, "no, the word conjugate embraces the entire mixture." But, we are not contesting that on our primary argument on appeal. Our primary argument on appeal is that not only the monomers with no cross-linking, but the dimers and the trimers, which have only end-to-end cross-linking, meet all the limitations of the claims. They have a linkage to a terminal portion without significant cross-

before us, therefore, is whether the other components of the vaccine, the dimers and trimers which have protein linkages at both terminal portions of the Hib polysaccharides and exhibit end-to-end crosslinking, come within the meaning of the above-quoted language, in which case the totality of the accused product would be infringing.

The district court construed this phrase as being limited to linkage at only one terminal portion of the polysaccharide, excluding all crosslinking, even end-to-end crosslinking. Accordingly, the court held that the claims did not cover the dimers and trimers in HibTITER. NRC argues that the court's claim interpretation was erroneous and that the limitation requiring "linkage to a terminal portion of the polysaccharide without significant crosslinking" in claim 11 is not limited to linkage at only a single terminal, but includes linkages at either one or both terminals of the polysaccharide. According to NRC, end-to-end crosslinking which involves linkages at both terminal portions of the polysaccharide is not "significant crosslinking" for purposes of the asserted claims since it achieves the intended purpose of the invention by avoiding crosslinking along the backbone of the polysaccharide. NRC also argues that the inclusion of references to *Haemophilus influenza* in dependent claim 12 and the specification indicate that claim 11 was intended to be interpreted to include end-to-end crosslinking because polysaccharides from that organism lead to end-to-end crosslinking. Thus, NRC asserts, the properly interpreted claims cover the dimers and trimers in HibTITER. We disagree and conclude that the contested phrase does not include polysaccharide-protein linkages at both terminal portions of the polysaccharide.

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linking. And therefore, when the claims are properly construed, then all the molecules in the entire product meet the limitations of the claim, irrespective of whether conjugate means a single molecule or all the molecules. *So I don't think conjugate is really an issue on this appeal, your Honor.*

Transcript from oral argument (emphases added).

A determination as to the scope and meaning of a claim is a question of law which we review *de novo*. *ZMI*, 844 F.2d at 1578, 6 USPQ2d at 1559. Therefore, we need not defer to the district court's claim interpretation. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988) (citation omitted). Cyanamid characterizes these issues as questions of fact, imposing on us a "clearly erroneous" standard of review. It argues that the meaning of claim language raises factual questions. We agree that a genuine evidentiary conflict underlying the meaning of claim terms raises a question of fact, but the questions before us in this case go to the heart of what the claims mean. Resolution of disputed issues regarding the meaning of contested language is ultimately a determination of what claims mean and what they cover. It is a matter of law for this court to decide without special deference to the district court. Absent "a genuine evidentiary conflict created by the underlying probative evidence pertinent to the claim's interpretation[,] . . . claim interpretation may be resolved as an issue of law by the court taking into account the specification, prosecution history or other evidence . . . ." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1579-80, 12 USPQ2d 1382, 1386 (Fed. Cir. 1989) (citations omitted).

In construing claims, we begin with the language of the claims themselves. *SmithKline Diagnostics, Inc. v. Helena Lab., Corp.*, 859 F.2d 878, 882, 8 USPQ2d 1468, 1472 (Fed. Cir. 1988) (citations omitted). Claim 11 specifically refers to "a terminal portion"; it does not refer to "any terminal portion" or to "all terminal portions." While it is generally accepted in patent parlance that "a" can mean one or more, *see* Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* 531 (3d ed. 1990) ("In a claim, the indefinite article A or AN connotes 'one or more.' "), there is no indication in the patent specification that the inventors here intended it to have other than its normal singular meaning.

When the meaning of a claim term is in doubt, we look to the specification for guidance. *See Hormone Research Foundation, Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1562, 15 USPQ2d 1039, 1042 (Fed. Cir. 1990), *cert. dismissed*, 111 S. Ct. 1434 (1991). In doing so here, we find no indication in the patent specification that the inventors intended to included end-to-end linkages within the scope of their invention. All references to polysaccharide linkages speak of a linkage, not multiple linkages. For example, the summary of the invention describes the formation of the protein linkage to a terminal portion of the polysaccharide as follows:

> We have found it possible to introduce *a free aldehyde group* into the polysaccharide molecule in *a terminal location* and to specifically couple *this aldehyde group* to protein without activating other functional groups on the polysaccharide.

Col. 2, lines 33-37 (emphasis added.) Similarly, the specification states:

> The reductive amination covalently couples *the terminal aldehyde group* of the polysaccharide to a free amino group on the protein through *a* $-CH_2NH-$ *protein linkage where the* $-CH_2-$ *derives from the aldehyde group*. There is no significant cross-linking by this method . . . .

Col. 3, lines 55-64 (emphasis added.) Reference to "the" terminal aldehyde group is consistent with linkage at only one terminal, not at both.

The examples in the specification also support linkage at only one terminal. In teaching the selective periodate oxidation of meningococcal polysaccharide, the specification states that "[t]he oxidized polysaccharides now had a terminally-located aldehyde group." Col. 5, lines 14-15. Use of the term "a" and reference to "group" in the singular shows that the specification teaches linkage at only one terminal portion. Furthermore, in teaching the

direct conjugation of the oxidized polysaccharides with proteins, the specification states:

> *It is unlikely that the reducing terminal sialic acid residue at the opposite end would oxidize to any great extent* using these conditions because it exists in solution mainly in its pyranose ring form and such has been found to behave similarly to an interchain residue.

Col. 5, lines 50-54 (emphasis added.) This statement shows that it is "unlikely" to obtain linkage at both terminals. Similarly, with respect to meningococcal group A polysaccharide, the specification teaches:

> *[T]he reducing end-group N-acetyl-mannosamine residue was made into the most susceptible residue* by simply reducing it to its open chain N-acetylmannosaminitol derivative. In this form, the modified group A polysaccharide was selectively oxidized *at this residue* to generate *a terminally-located aldehyde group.*

Col. 5, line 67—col. 6, line 5 (emphases added.) Again, reference to "the" reducing end group, "this" residue, and "a" terminal aldehyde are consistent with linkage in the singular.

NRC argues that the "significant crosslinking" that the inventors intended to avoid was not end-to-end crosslinking, but crosslinking across the backbone of the polysaccharide molecule. While such an interpretation might make sense as a theoretical concept, it has no support in the specification. The word "backbone" does not appear in the specification, nor does the concept of avoiding linking other than at multiple terminal portions. Contrary to NRC's argument that "significant crosslinking" is crosslinking along the backbone of the polysaccharide, the specification states:

> The reductive amination covalently couples *the terminal aldehyde group* of the polysaccharide to a free

> amino group on the protein . . . . *There is no significant cross-linking by this method* . . . .

Col. 3, lines 55-64 (emphases added.) The above-referenced statement that linkage to *the* terminal portion results in "no significant crosslinking" shows that "significant crosslinking" for purposes of the claims was not intended to mean linking along the backbone as NRC urges, but linking at more than one terminal.

It is the responsibility of patent applicants to disclose their inventions adequately. 35 U.S.C. § 112. There is no such disclosure of the concept of avoiding crosslinking along the backbone in this patent. Thus, an invention of that breadth does not meet the *description requirement. See Carmen Industries, Inc. v. Wahl*, 724 F.2d 932, 937 n.5, 220 USPQ 481, 485 n.5 (Fed. Cir. 1983) ("Claims should be so construed, if possible, as to sustain their validity.") (citations omitted). As explained above, the examples are consistent with monofunctionality, not difunctionality. A patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent. One of the inventors, Dr. Jennings, testified that he intended to include difunctional molecules within the scope of his invention. Such after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself. *See Senmed, Inc. v. Richard-Allen Medical Indus. Inc.*, 888 F.2d 815, 819 n.8, 12 USPQ2d 1508, 1512 n.8 (Fed. Cir. 1989) (Where meaning of claim term is clear from specification and prosecution history, the inventor's "self-serving *post-hoc* opinion testimony on the legal question [] whether it should have a different meaning was of little if any significance.") (citation omitted).

NRC argues that inclusion of the words *Haemophilus influenza* in the dependent claims and specification prove

that difunctional molecules are within the scope of claim 11 because such organisms lead to difunctional products according to this invention. While it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog. Certainly in this case, as we have indicated, there is no further disclosure or description in the specification of difunctional molecules resulting from *H. flu* or any other organism. Moreover, the district court did not find that *H. flu* always yields a difunctional result, as NRC asserts, but found that one of the "five or six" *H. flu* serotypes "is the one which yields the difunctional result." 24 USPQ2d at 1903.

There also was evidence at trial contrary to NRC's assertion that use of *H. flu* always results in difunctionality. Dr. Eby, one of Cyanamid's expert witnesses, testified that the *H. flu* polysaccharide could be treated to create only a single aldehyde that would result in monofunctionality and that such monofunctional *H. flu* polysaccharides could have been made by one skilled in the art in 1981 when the patent application was filed. Dr. Eby explained that the reference to *H. flu* in claim 12 is completely consistent with monofunctionality, thereby providing a basis for its inclusion consistent with the otherwise clear singular meaning of "a terminal portion." Thus, use of the words *Haemophilus Influenza* in claims 12 and 25 is not inconsistent with a monofunctional interpretation of claim 11.

Finally, if we were to interpret claim 11 on the basis of NRC's argument concerning what claim 12 requires, claim 11 would include polyfunctional molecules, which are concededly not within the scope of the invention. That cannot be what NRC intends. We therefore conclude that "linkage to a terminal portion" includes linkage only to "a terminal portion" at one end of the polysaccharide.

Since we have interpreted the expression "a terminal portion" to include only monofunctionality, it is clear that the limitation "without significant crosslinking" excludes from the claims linkage other than monofunctional linkage. End-to-end crosslinking, consisting of protetin linkages at both terminal portions of a polysaccharide, is inconsistent with the clear meaning of the expression "a terminal portion." Thus, end-to-end crosslinking is "significant crosslinking" in terms of this patent and it is excluded from the claims. As noted earlier, the specification does not use the term end-to-end crosslinking or difunctionality, nor does it use any language which conveys that backbone crosslinking was excluded, but end-to-end crosslinking was not. As for the term "significant," it is undisputed that 50% of the polysaccharide-protein molecules are other than monofunctional, that they have end-to-end crosslinking. There is no basis for concluding that 50% is not significant. Finally, it is the responsibility of patent applicants to define their inventions adequately. In the absence of any definition of this term in the specification, NRC cannot complain if its after-the-fact definition is not accepted. Thus, the district court correctly construed the claim in concluding that end-to-end crosslinking did not meet the limitations of the claims.

Cyanamid, as did the district court, emphasizes an article and speech of Dr. Jennings, one of the named inventors on the patent, in which he described his research on polysaccharide-protein conjugates as directed toward achieving monofunctionality. Jennings made these presentations at about the same time as he filed his patent application. The court concluded that Jennings' failure to clearly express in his application his intention to claim more than the monofunctional product of his earlier work showed that the claims were limited to the scope of his earlier work. 24 USPQ2d at 1902.

Cyanamid argued before us that the court correctly concluded that the monofunctional approach embodied in

Jennings earlier work was carried over into his patent. According to Cyanamid, Jennings' article and speech show the "evolution" of the patent and compel a claim construction to require monofunctionality. While we have affirmed the district court's interpretation of the claims, we must reject its doing so on the basis of this argument. A patent is to be interpreted by what it states rather than by what the inventor wrote in a scientific publication.

There is no inconsistency between writing a paper (or giving a speech) on a particular embodiment of an invention and then claiming one's invention more broadly in a patent application. Patents often teach embodiments not carried out in the laboratory; scientific papers rarely do. Thus, it was error, albeit harmless error, for the distict court to conclude that the narrow scope of the article limits the scope of the patent claims, which should be judged on their own merits.

Having construed the claims, the next determination is infringement. Accordingly, we must determine whether the court clearly erred in holding that the claims do not read on HibTITER. As stated above, the characteristics of HibTITER are undisputed. The only issue is whether the phrase "linkage to a terminal portion of the polysaccharide without significant crosslinking" reads on the HibTITER product as a whole, which, in view of NRC's concession at oral argument,[3] requires determination whether the phrase reads on a product which includes dimers and trimers as well as monomers. In view of our decision that this phrase covers linkage at only one terminal portion of the polysaccharide and does not include

[3] The dissent, in its commentary on claim 25, ignores the clear and unmistakable concession by NRC that it is not challenging the trial court's ruling that "conjugate" means the mixture of molecules as opposed to individual molecules. Whatever NRC's reasons, we do not review what it chooses to accept. Moreover, if claim 11 is not infringed, as we have concluded, dependent claim 25 cannot be.

end-to-end crosslinking, the HibTITER product including dimers and trimers clearly is not within the scope of the claims. Accordingly, the district court did not clearly err in concluding that HibTITER does not infringe claims 12 and 25.[4]

B. *Validity*

The district court concluded that claims 12 and 25 were invalid for indefiniteness under 35 U.S.C. § 112, second paragraph, which requires that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Even though we have affirmed the district court's decision of noninfringement, we find it desirable to review this holding of invalidity. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 113 S. Ct. 1967, 26 USPQ2d 1721 (1993). NRC is entitled to have the validity of its claims considered rather than have the district court's judgment merely vacated, leaving a cloud on the patent. Future modification of Cyanamid's product, or sale by another party, could raise questions of infringement of the claims as we and the district court have construed them. Finally, since we have thoroughly reviewed the case, no added judicial effort is involved.

The underlying basis for the court's conclusion of invalidity on the ground of indefiniteness was the parties' stipulation that the five categories of polysaccharides recited in claim 12, and the two categories recited in claim 25, each include a number of members (serotypes) which, when treated according to the teachings of the '170 patent, would result in polyfunctional molecules, polysaccharides

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[4] The dissent argues at great length that the specification "reveals the inventors' intent" that cross-linking only means backbone cross-linking, and that "a terminal portion" includes two terminal portions. It refers to the specification's "clear meaning" and that it "clearly did not limit the claims." The plain fact, however, is that these matters are not clear at all and that the specification contains no express disclosure of difunctional molecules.

having protein linkage along their backbones. This result is outside the scope of claim 11 and contrary to the teachings of the patent. On the basis of this fact, the court held the claims indefinite, stating that "there are so many different kinds of polysaccharides referred to which would yield different results, polyfunctional, difunctional and monofunctional, some of which results are admittedly contrary to the patent's teaching." 24 USPQ2d at 1903. NRC argues that the court's conclusion was erroneous. Specifically, NRC asserts that Cyanamid failed to meet its burden of proving that the claims are indefinite, and that the parties' stipulation was an insufficient basis for the court's holding that the claims are invalid. We agree with NRC that the parties' stipulation of possible inoperativeness of some species does not constitute an admission that those skilled in the art would not be reasonably apprised of the scope of the claims.

Under 35 U.S.C. § 282 (1988), a patent is presumed valid, and at trial Cyanamid had the burden of proving facts by clear and convincing evidence showing that the patent is invalid. *See Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463, 7 USPQ2d 1325, 1326-27 (Fed. Cir. 1988). Compliance with the definiteness requirement is a question of law which we review *de novo*. *Carl Zeiss Stiftung v. Renishaw plc*, 945 F.2d 1173, 1181, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991). Whether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088, (Fed. Cir. 1986) (citations omitted).

Cyanamid did not meet its burden under the clear and convincing standards to show that one of ordinary skill would not understand what is included within claims 12 and 25. Claim 11, the claim from which claims 12 and 25 depend, requires linkage at a terminal portion of the

polysaccharide. The specification is clear that the claimed invention relates to conjugates having a protein linkage at a single terminal portion of the polysaccharide, not at both terminal portions. Thus, while the parties in the midst of a dispute have disagreed concerning the meaning of the claims, the claims are not so lacking in clarity as to be invalid under section 112.

The categories of polysaccharides recited in claims 12 and 25 do include numerous members (serotypes), some of which apparently result in polyfunctional molecules when treated according to the teachings of the patent. The fact that dependent claims include species which might not meet the objects of the invention does not by itself prove that one skilled in the art cannot ascertain the scope of the asserted claims. That objection goes to possible inoperativeness under 35 U.S.C. § 101 or lack of enablement under 35 U.S.C. § 112, first paragraph, neither of which provisions are before us. Moreover, if a species within a dependent claim does not meet the limitations of the independent claim, arguably it is not included within the scope of that dependent claim.

The law is clear that " '[i]f the claims, read in the light of the specification[s], reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Shatterproof Glass Corp. v. Libbey-Owens Ford, Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.), *cert. dismissed*, 474 U.S. 976 (1985) (quoting *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136, 118 USPQ 122, 132 (2d Cir.), *cert. denied*, 358 U.S. 884 (1958)). That is the case here.

NRC's expert, Dr. Schoolnik, testified on cross-examination that, in view of the teaching in the specification to avoid protein linkage along the backbone of the polysaccharide, he would know that the polysaccharides recited in claims 12 and 25 refer only to the serotypes

that would result in "a clean backbone when the procedures recommended by [the] patent are performed on those structures." He testified:

> [I]t's understood by everyone working in the field that you first draw out from [the group of bacterial types in claim 12] the particular types that are relevant to infantile meningitis, and then I think, as a scientist, I would look at the structure of the polysaccharides from those types and I would say are they structures that would, when subjected to this process, leave a backbone that's antigenic and probably, therefore, effective as a vaccine.

We conclude that the claims are sufficiently clear to apprise those skilled in the art of their scope. We thus reject Cyanamid's argument that indefiniteness "follow[s] directly from stipulated facts," as that stipulation was insufficient as a matter of law to sustain the court's holding that claims 12 and 25 are indefinite. Accordingly, we conclude that the court erred in its holding of invalidity.

CONCLUSION

The court did not err in holding claims 12 and 25 of the '170 patent not infringed, but did err in holding them invalid. Accordingly, the judgment of the district court is affirmed-in-part and reversed-in-part.

COSTS

No costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART

RADER, *Circuit Judge*, dissenting.

I agree with this panel that the district court erroneously concluded that claims 12 and 25 were invalid for indefiniteness. I also agree that the district court erred in relying on the inventors' scientific articles to determine the scope of the claims. Unfortunately, I cannot support the rest of this court's opinion.

As the panel points out, the district court erroneously based its decision on the inventors' articles in scientific journals. Although a patent specification may supply guidance about the meaning of claim terms, *Hormone Research Foundation v. Genentech, Inc.*, 904 F.2d 1558, 1562, 15 USPQ2d 1039, 1043 (Fed. Cir. 1990), scientific literature differs in purpose, scope, and legal effect from patent writings. Because inventors generally have extraordinary skill, their scientific writings outside the patent are rarely even a source of knowledge about ordinary skill in the art. The panel's opinion correctly notes the trial court's error in relying extensively on the inventors' scientific articles for its claim interpretation. The trial court referred to the scientific writings as "the most important point in the evidence." Surprisingly, however, the panel's opinion did not consider this error a cause for reversal. In a case the district court repeatedly characterized as "very close," this extensive reliance on impermissible evidence constitutes reversible error. Without the primary source of evidence upon which the district court based its decision, this "very close" case would no doubt have ended differently.

The majority suggests that the meaning of the term "conjugate" was conceded by North American Vaccine. In context, however, it appears that counsel was only trying to argue that the interpretation of the term "conjugate" is not dispositive. Moreover, plaintiff's reply brief actually contests the majority's interpretation and argues that the district court's ruling was incorrect. The majority hinges its conclusion on an equivocal statement

made to pursue a more important concern. This approach appears unwarranted under the circumstances.

Claim 11—"at a terminal portion"

An examination of the claim language shows that the district court's use of impermissible evidence infected the judgment in this case. Claim 11 requires linkage of a protein "to a terminal portion of the polysaccharide." The accused product literally reads on this requirement. The panel's opinion and both parties concede: "The protein linkage in each of these components is at *a terminal portion* of the Hib polysaccharide . . . ." Slip Op. at 4, lines 8-10.

A branched polysaccharide, however, can have two or more terminal ends. The accused product linked protein at two of these terminal ends. The trial court, relying on the inventors' scientific writings about "monofunctionality" or "monovalency" (technical terms for linkage at a single terminal end), interpreted the claim language to mean that any more than a single link at a terminal end escapes infringement.

The claim, however, does not require linkage "at a *single* terminal portion of the polysaccharide," but simply "at a terminal portion." The trial court used extraneous scientific writings to create a limitation—at a *single* terminal portion—not found in the claim language. Indeed in patent claims, the indefinite article "a" may denote one or more objects. Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* 531 (3d ed. 1990) ("In a claim, the indefinite article A or AN connotes 'one or more' ").

Thus, according to the claim language, each link at a terminal portion of the polysaccharide reads on the claims. American Cyanamid infringed the patent by linking a protein to "a terminal portion" of the polysaccharide. When American Cyanamid linked a protein to two

terminal ends, it still linked to "a terminal end" and infringed the claim. American Cyanamid indisputably always links at a terminal portion of the polysaccharide, but argues that the trial court correctly read "a terminal portion" to mean "a single terminal portion." The claims simply do not contain that limitation.

If the trial court had properly relied on the patent specification or prosecution history to construe the claims, it would have noted that these correct patent sources do not even mention "monofunctionality" or "monovalency." A comparison of the inventors' scientific writings with their later patent writings shows a complete deletion of all references to "monofunctionality" or "monovalency." Ironically, the scientific writings, in the proper context of the patent, show that the inventors—by deleting references to "monofunctionality"—clearly did not limit the claims to linkage at a single terminal end.

The panel's opinion recognizes the trial court's error in its extensive reliance on impermissible evidence. Nonetheless the panel compounds the error by creating on its own the same limitation. The panel purports to find this limitation in the specification.

In the first place, this court of appeals prohibits importation of limitations from the specification into the claims. *In re Lundberg*, 244 F.2d 543, 548, 123 USPQ 530, 534 (CCPA 1957). The panel's belated discovery of a limitation to a "linkage at only one terminal portion" in the specification should still not influence its reading of the claims. Slip Op. at 9, lines 17-18.

To my eyes, however, the specification does not contain anything close to the "only one terminal portion" limitation. As already noted, the specification never refers, even obliquely, to monofunctionality, i.e., linkage to a single terminal end. The panel perceives this monofunctionality in the singular references to terminal linkages and in a single example in the specification.

The singular references in the specification are an effort to preserve grammatical accuracy, not create a limitation. The specification adopts the same grammatical number as the terms in the claims. Because the claims discuss each terminal end separately, the specification does the same. Naturally, therefore, the specification uses the singular number. The specification does not demonstrate monofunctionality; rather, good grammar.

The specification's example from the meningococcal group of polysaccharides also does not create a limitation missing from the claims. This example discussed one element only of the Markush groups of claims 12 and 25. Monofunctionality in a single member of the Markush group does not mean all members of the group can only produce a single linkage. By narrowly construing the example and importing that construction into the claim, the panel in effect limits the patent to a single example in the specification. This single example simply does not, and should not, limit the entire claim.

A specification can supply understanding of unclear claim terms, but should never trump the clear meaning of claim terms. *E. I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1443, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988). Moreover a specification should have a clear and distinct message before it influences claim meaning at all. In this case, the panel exalts the specification—without a single express reference to "monofunctionality" and without any unambiguous reference limiting linkages to a single terminal—over the express meaning of claim terms.

Not only did American Cyanamid literally infringe by linking to "a terminal portion," it chose precisely the polysaccharide mentioned in dependent claims 12 and 25—the polysaccharide of *H. influenza*. Moreover, the trial court found that the *H. influenza* polysaccharide links at more than one terminal end. Therefore, these dependent claims show that claim 11's language em-

braced each protein link "at a terminal portion." Not only does American Cyanamid literally infringe claim 11, it does so with precisely the polysaccharide in claims 12 and 25.

Claim 11—"without significant cross-linking"

Claim 11 also contains the phrase "without significant cross-linking." The term "cross-linking" could apply to three types of bonds: (1) the covalent bond between the protein and the polysaccharide polymers, (2) any linkage randomly located on the polysaccharide, and (3) a linkage at "a terminal portion of the polysaccharide" in the presence of another linkage. The claims exclude from the term "cross-linking" the type (1) bond because the claims call such a bond simply a "linkage". The specification includes the type (2) bond within "cross-linking." The Background section of the patent indicates that these random linkages along the polysaccharide were a problem in the prior art which the invention cures. Neither the claims nor the specification include the type (3) bond, linkage at "a terminal portion of the polysaccharide," within the realm of "significant cross-linking." In fact, the conspicuous absence of the terms "monofunctional", "monovalent", and their equivalents from the specification suggest that the type (3) bonds are not the "significant cross-links" which the invention sought to avoid.

Indisputably, the terms of the claim preclude the type (1) bond as the prohibited cross-link. The specification expressly discusses the random type (2) bonds as the cross-links which reduced the conjugant's benefit as an antigen in the prior art. The patent discussed "significant cross-linking" only in the context of avoiding the prior art problem with "many randomly activated functional groups . . . on the various polysaccharides leading to considerable cross-linking." *See* Col. 2, lines 14-18. The invention specifically sought to avoid this type of random cross-linking. For this reason the claim expressly forbid "significant cross-linking." Thus, according to the spe-

cification, the "significant cross-linking" prohibited by the claims refers to type (2) bonds.

Furthermore, the specification also points out that the invention permits a difference between reactivity along the group C polysaccharide chain and reactivity at a terminal end. *See* Col. 5, lines 50-54. These interchain linkages—the random type (2) bonds—display less reactivity than linkage at terminal ends. The inventors further explain that the interchain 2—8 linkages of the group B polysaccharide are even less likely to react under the conditions of the invention. *See,* Col. 5, lines 54-59. By noting this distinction, the specification reveals the inventors' intent to avoid interchain cross-links: Inexplicably the panel overlooks this additional evidence that the invention intended the "without significant cross-linking" limitation to mean type (2) interchain linkages, the inventors' term for linkages along the backbone of the polysaccharide.

In the face of this clear evidence of the meaning of "without significant cross-linking," the trial court found that the type (3) bond was the forbidden form of cross-link. Again the trial court's reliance on impermissible evidence caused this error. Based on this external evidence, the district court incorrectly decided that the claim embraced only monofunctional linkages.

The panel again embraces the decision reached by the trial court's clear error. In this case, however, the panel cannot draw credible support for its position from the specification. The patent specification clearly suggests that "without significant cross linking" refers to "many randomly activated functional groups" and not to cross-linking at a terminal portion of the polysaccharide.

More importantly, the panel overlooks the language of the claims. The claim language discusses linkage "at a terminal portion" specifically and then generally prohibits "significant cross-linking." The specific reference to

terminal portion linkage suggests that the general cross-linking language refers to something other than terminal portion linkage. Striving to justify its importation of monovalency into the claim terms, the panel construes "cross-linking" as the type (3) bond. In doing so, however, the panel disregards the language of the claims and the clear meaning of the specification.

Claim 25

Neither the trial court nor the panel adequately explains how the accused composition avoided infringement of claim 25. Even construing "without significant cross-linking" to mean "with absolutely no cross-linking," the accused product still infringes claim 25. Claim 25 uses open ended "comprising" terminology. The claim requires only that the vaccine contain a *component* which is (i) an *H. influenza* polysaccharide, (ii) antigenic with a molecular weight (M_w) above 2,000, (iii) a polysaccharide:protein coupled via -CH_2-N-protein linkage to "a terminal portion of the polysaccharide," and (iv) "without significant cross-linking." American Cyanamid's accused product contains a *component* which the trial court called a "monomer." Dr. Eby, Cyanamid's own expert witness, testified that 50% of the accused product was this "monomer" component. Both parties agree and the district court found that this monomer component is a non-cross-linked species of protein linked to polysaccharide. Therefore, this component is (i) an *H. influenza* polysaccharide, (ii) antigenic with a M_w above 2,000, (iii) a polysaccharide:protein coupled via -CH_2-N-protein linkage to "a terminal portion of the polysaccharide," and (iv) "without significant cross-linking." By the definition, this product with 50% infringing material infringes the open-ended claim 25.

American Cyanamid merely took a patent on A, B, C —(A) *H. influenza* polysaccharide (B) linked at a terminal portion to protein (C) without significant cross-

linking—and added a new element, D. The new element, D, is material ("dimers" and "trimers") linked at more than one terminal position. Adding some "dimers" to the infringing "monomer" material does not defeat infringement. Adding an additional component D does not defeat infringement of an open-ended claim to A, B, C. *Loctite Corp. v. Ultraseal, Ltd.*, 781 F.2d 861, 865, 228 USPQ 90, 92 (Fed. Cir. 1985) ("It is uncontested that Ultraseal's PC504 contains a monomer and an initiator selected from the monomers and initiators of the patent claims. Though PC504 also includes components not required by the claims, such inclusion does not avoid infringement. . . .") (footnote omitted); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1484, 221 USPQ 649, 655 (Fed. Cir.), *cert. denied*, 469 U.S. 942 (1984); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703, 218 USPQ 965, 967 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1042 (1984) ("It is fundamental that the one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device").

Overlooking claim 25's language totally destroys the value of the patent. Potential infringers need only add an additional component, i.e., some "dimer" material, to avoid infringement. Thus, even adopting the trial court's strained interpretation of "conjugate," I would reverse the trial court's judgment of non-infringement on claim 25.

Conclusion

This claim is not ambiguous. It clearly requires only linkage "at a terminal portion." Nonetheless the Supreme Court's admonition applies here: "if the claim [is] fairly susceptible of two constructions, that should be adopted which will secure to the patentee his actual invention." *Smith v. Snow*, 294 U.S. 1, 14 (1935). The record also shows American Cyanamid could not create "[a]n antigenic-polysaccharide:protein conjugate wherein

the polysaccharide and protein are covalently linked through a CH_2-N-protein linkage to a terminal portion of a polysaccharide," until shortly after gaining access to the inventors' work. In the face of evidentiary errors by the trial court in conflict with the meaning of the claims, I would remand.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

93-1076

NORTH AMERICAN VACCINE, INC. and
NATIONAL RESEARCH COUNCIL OF CANADA,
Plaintiffs-Appellants,

v.

AMERICAN CYANAMID COMPANY and
PRAXIS BIOLOGICS, INC.,
Defendants-Appellees.

On Appeal from the United States District Court
Southern District of New York
in Case No(s). 91-CV-1449

JUDGMENT

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

AFFIRMED-IN-PART AND REVERSED-IN-PART

DATED Oct. 6, 1993

ENTERED BY ORDER
OF THE COURT

/s/ Francis X. Gindhart
FRANCIS X. GINDHART
Clerk

Issued as a Mandate: December 15, 1993

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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91 Civ. 1449 (TPG)

NORTH AMERICAN VACCINE, INC., *et al.*,
Plaintiffs,

-against-

AMERICAN CYANAMID COMPANY, *et al.*,
Defendants.

OPINION

[1801] THE COURT: I'd like to now put my findings and conclusions on the record, and I do that with this preface:

This has obviously been a long and complicated case, and I'm sure that it might appear foolhardy to try to render a bench decision. But for me what is important is to make my ruling while I have in my mind, and fresh in my mind, the benefit of all the hard work that has gone on by the lawyers and all the rather vigorous interchanges that have gone on between me and the lawyers.

Now, I'm going to put down on the record with the court reporter my findings and conclusions.

After that, the parties can see the transcript, and if they have any feelings about something that is left out that hasn't been covered, they can request an amendment of the findings. But all that process will be over with, I would say, within a week, and I think a lot is to be gained by doing it this way.

I do not intend to discuss all the evidence. I do not intend to discuss the pros and cons and significance of even a substantial part of the evidence. What I am going

to do is to make my findings and my conclusions with some relatively brief explanation.

I have been furnished with legal authorities, both at the beginning of the trial and at various points through the trial, and I have considered the relevant [1802] authorities, although I do not intend to cite them specifically in this statement.

Now, let me repeat what I have indicated before, and that is that the case has been presented in the most remarkable manner. The skill and thoroughness and fairness and courtesy of all the participants have been an absolute model. The examination and cross-examination, all those things have done their job. It wasn't a wasted effort in any way.

And certain of the attorneys have been spokesmen for their clients, but obviously there has been a lot of very hard work by the staff that helped those attorneys, and all of that has produced a trial with very fine organization and elucidation of the subjects.

I think the case is a close one. That means that the plaintiffs have powerful points in their favor. Those points have been expressed with great weight by Mr. Diaz and his colleagues. The defendants have powerful arguments in their favor. Those arguments have been expressed by the attorneys for the defense.

The decision has to be made, and I believe that the scales tip, not drastically, but I think they tip in favor of the defense.

The case, of course, involves patent number 4,356,170. The application was filed May 27, 1981. It was [1803] issued October 26, 1982. The principal inventor is Harold J. Jennings of Ottawa, Canada. Also listed as an inventor is Mr. Czeslaw Lagowski.

The plaintiffs are North American Vaccine, Incorporated, and National Research Council of Canada. The suit is a claim for patent infringement. It is brought against American Cyanamid Company and Praxis Biologics, Inc.

The patent relates to certain technology involved in vaccines. Neither Dr. Jennings, nor the other inventor, nor the plaintiffs have actually produced a vaccine or any product based on the patent. However, Cyanamid and Praxis have produced a vaccine called HibTITER, which is intended to deal with a particular kind of meningitis. That vaccine is highly successful, and the claim is that that vaccine infringes certain claims of the '170 patent, specifically, claims 12 and 25.

The question which has been involved in most of the evidence and argument of this trial is the question of interpretation of claims 12 and 25.

I think it is safe to say that if claims 12 and 25 were to be interpreted in accordance with plaintiffs' position here, it would not be difficult to find infringement.

So the basic question upon which the infringement issues depend is how should we interpret claims 12 and 25. [1804] Since this is an infringement case, and the plaintiffs have the burden of proof on infringement, I believe it is safe to say they have the burden of proof to show their particular interpretation, as that is foundational to the infringement issue.

Now, claim 12 and claim 25 are both dependent upon claim 11, and it is necessary to read into the record claim 11, which is as follows:

"An antigenic-polysaccharide:protein conjugate wherein the polysaccharide and protein are covalently linked through a CH2-HN-protein linkage to a terminal portion of the polysaccharide without significant crosslinking, said antigenic polysaccharide having a MW above about 2,000."

Now, claim 12 reads as follows:

"The conjugate of claim 11 wherein the antigenic polysaccharide is selected from the group derived from meningococci, Haemophilus influenza, pneumococci, B-hemolytic, streptococci, and E. coli."

Claim 25 reads as follows:

"A human infant vaccine comprising the conjugate of claim 11 wherein the polysaccharide comprises at least one of meningococcal polysaccharide and Haemophilus influenza polysaccharide."

Now, although claim 11 is not literally referred to in the infringement cause of action, it is foundational [1805] and its interpretation is crucial to a resolution of this case.

There are several issues about the meaning of claim 11. One is what is meant by the word "conjugate". I'll come back to that later. The most serious issue relates to the phrase "a terminal portion of the polysaccharide without significant crosslinking." The phrase "a terminal portion" is, of course, in the singular.

The defense contends that this singular phrase should be interpreted as just that: as providing for linkage at one terminal portion of the polysaccharide. This is a crucial point because the vaccine produced and marketed by defendants involves the use of polysaccharides, which have linkages at both terminal portions at both ends.

A polysaccharide can be viewed as being a string. A string has two ends. HibTITER has the chemical linkage at each end, at both ends, at both terminal portions. Thus, it is crucial to defendant's case to urge upon the Court that the language in claim 11 should mean literally what it says: that it is a claim in which there is to be linkage at one terminal portion of the polysaccharide, not at both ends, not at each end.

There was extensive evidence at the trial about the background of Dr. Jennings' invention, the technology which existed at the time of his invention, the problems in [1806] the immunization of people who were sought to be immunized against certain diseases.

The polysaccharide was known to be important in creating the kind of vaccines that Dr. Jennings and other scientists were working on. There were various problems in the use of these polysaccaharides. One of these prob-

lems was the question of how the polysaccharide would be introduced into the system of the person being vaccinated or immunized, and the focus of the particular work was upon infants, very small infants.

Their needs as far as immunization were different from older children and from adults, and the evidence in this case indicates that one way, and perhaps the only way, but at least one way of getting the polysaccharide introduced into the system of the infant was to have it linked to a protein, or perhaps more than one protein, and the protein would carry out the job of getting it into the system of the infant. And that is why claim 11 talks about linking a protein to a polysaccharide.

Now, some of the work in this field involved methods which placed a great deal of protein matter on the polysaccharide, that protein matter being distributed all along the length of the polysaccharide. The problem with this was that there was too little polysaccharide left exposed, and I think the evidence refers to this problem as [1807] being that the immune system of the infant would not recognize the polysaccharide. In any event, covering the polysaccharide with protein or having a lot of protein along the length was a problem.

As we know from the evidence in this case, that which I have just called a problem perhaps was not perceived by everyone as a problem, because certain parties developed products in which this situation occurred where there was protein distributed along the length of the polysaccharide. But at least to some scientists it was viewed as a problem, and certainly it was viewed as a problem by Dr. Jennings.

If we just stepped away from the chronology of the developments and thought in an abstract way, we might say that the issue of having protein distributed along the length of the polysaccharide might be solved if the protein were placed at one end of the polysaccharide, or, in the language of claim 11, at a terminal portion of the polysaccharide.

Again, speaking somewhat abstractly, one might say that the problem of having protein distributed along the length of the polysaccharide might be solved by having protein distributed at the two ends, the two terminal portions, provided that the portion was not massive or the polysaccharide was not so short that this somehow obscured the polysaccharide.

[1808] But given proper proportions of the polysaccharide and protein, it is not difficult to conceive of the issue under discussion as being taken care of by a polysaccharide having a protein at one end or having a protein at two ends.

Now, it is time to mention the issue of crosslinking. Crosslinking refers to a situation where a polysaccharide acts as a link between two proteins. If proteins are located all along the length of a polysaccharide, there are many crosslinks. Each space on a polysaccharide between two proteins is a crosslink.

There are other ways in which crosslinking can come about creating structures that look like networks. This results in what some perceive as a problem in defining the exact structure.

If there is a great deal of crosslinking and different kinds of networks, the definition of the substance, the definition of the molecular shape becomes more and more vague and more and more diffuse. Crosslinking also affects the solubility. The more crosslinking, the less solubility.

It is a fact established in the evidence that where a polysaccharide has a protein linked at one end, there is no crosslinking. You can have several polysaccharides linked to one protein, but none of those [1809] polysaccharides are linked to two proteins, and thus there is no crosslinking.

When you have polysaccharides with protein all along the backbones, there is abundant crosslinking. Where you have polysaccharides with proteins at the two terminal ends, there is less crosslinking than in the situation just

mentioned, but there still will develop, as illustrated in the evidence in this case, a substantial amount of cross-linking.

Now we come back to the question of interpretation. Plaintiffs contend that the singular phrase "a terminal portion of the polysaccharide" is a kind of generic term and it is not intended and should not be interpreted to be limited to one single terminal portion. It should be interpreted to refer to a terminal portion at one end and also a terminal portion at the other end where there is such a thing.

In effect, plaintiffs wish to have the claim 11 language interpreted to mean a terminal portion of the polysaccharide at one or both ends.

As I have indicated, the defense position is that the claim 11 language means what it says, and refers only to a single terminal portion.

Now, as I've said many times during the trial, we cannot solve this problem by staring at the language and [1810] simply saying there is a singular indefinite article and a singular noun and that is that. It is perfectly possible, as an initial proposition, that the phrase "a terminal portion" is a generic term and could mean exactly what plaintiffs say it means.

In order to solve the problem, we need to look at some of the other evidence that can be considered properly under the law on the question of interpretation. We, of course, need to look at the other portions of the patent: the summary of the invention; the description of the experiments; other claims besides 11, 12 and 25. In other words, the whole patent.

In addition, there has been the testimony by the inventor, Dr. Jennings, and there has been discussed in the evidence at great length an article Dr. Jennings wrote in 1981 which was given by him to the drafter of the patent. That is Defendants' Exhibit F. Also referred to in our discussion of the case is a talk given by Dr. Jennings at the National Institute of Health in the fall of 1980, which

talk was embodied in an article which came out in 1982. This article is Defendants' Exhibit CT.

There is various other evidence relevant to the question of interpretation, including lengthy testimony by an expert called by plaintiffs, Dr. Harry Schoolnik of Stanford. I will not try to name all the witnesses, I will [1811] not try to sumarize all their testimony, but there has been a substantial amount of testimony and documents received into evidence bearing on the question of interpretation.

Perhaps the most important point in the evidence is the fact which is established without question, that is, that the laboratory work carried out by Dr. Jennings leading up to the patent was specifically designed to produce polysaccharides with protein linkage at only one end of the polysaccharide, that is, at one single terminal portion. [1812] In this work, it was not a matter of indifference to him whether one or two terminal portions were involved.

The testimony of Dr. Jennings, particularly on cross-examination, involved admission after admission about his desire in his experimentation to achieve what he called monofunctionality, which is another word for having the linkage at one end of the polysaccharide. He explained that he was doing this as a chemist, and he wanted a clear-cut chemical solution to the issues which I mentioned earlier. He wanted the clearest possible definition for the substance that he was creating. And therefore, he conducted experiments with the desire and the purpose of producing monofunctionality, that is, linkage at one terminal portion. This meant that cross-linking would be entirely avoided.

The only exception to this was that he knew that he might not be able to avoid some cross-linking because of some attachment of proteins at places other than the one terminal end, but this was something that would not come about by design, but only because in the world of chemistry, absolute purity might not be achieved. But he

sought, as he has admitted, the monofunctionality, which gave the best definition for the substance since it did not involve cross-linking.

This was made clear in his National Institute of Health speech and in the article he wrote in 1981. The [1813] speech and the article presented essentially the same concepts, described essentially the same experiments and described the same goals. For instance, in the article, he states as follows: "We have tried to extend the monofunctional group approach used in conjugating oligosaccharides to the larger molecular size meningococcal polysaccharides."

Later in the same article he states, "The ideal situation would be to specifically introduce one of these functional groups per polysaccharide molecule, preferably located in a terminal position."

Still later in the same article, he talks about monovalent polysaccaride molecules.

Let me say that were he speaks of functional groups, what is being talked about is a group not in the sense of one protein linked at one end and another linked at another end. But the group is a reference to a group of atoms, hydrogen, oxygen, and carbon.

Another expression that has been used at the trial is the word aldehyde, again referring to this grouping of the hydrogen, oxygen, and carbon atoms.

Now, there is simply no question about the fact that if the language of the 1981 article and of the NIH speech had been literally carried over into the patent, we really would have no issue here. It would be crystal clear [1814] that the patent related to monofunctionality. That is the idea of the linkage being at the one terminal portion of the polysaccharide. There really would be no problem with interpretation that anybody could sensibly raise.

However, the patent does not carry over the literal language of the NIH speech or the 1981 article. It does not use the word monofunctionality. It does not use the word monovalence. It does not literally say that Jennings is

trying to achieve one functional group. However, on some crucial points, certain language of the article and of the NIH speech are carried over into the patent and what has occurred is something which is rather odd in light of plaintiffs' contentions and Jennings's testimony here.

Jennings testified that when it came to taking out his patent, he intended to claim something broader than what he talked about in his speech and his article. He has testified that he did not intend his patent to be limited to monofunctionality. He has testified that his intent was to cover where the terminal linkage occurred at both ends of the polysaccharide.

Now it is clear that in the article and the speech, he was not talking about terminal portions at two ends, or what we call difunctionality. But he says when it came to drafting the patent, he intended to have his patent [1815] drafter broaden out his claims to cover the two terminal end situations.

And as already stated, he points to the fact that the word monofunctional and the word monovalent, those words are not present in the patent. The problem is that in some crucial respects, although he has left out those particular words, he has carried over other descriptive wording which was in the article and the speech which were tied in with the use of those words, monofunctional and monovalent. Thus, in the patent, those particular words are left out, but the descriptions which develop the concept of monofunctionality are carried over into the patent.

An example of this, I think, is worth reading, and I will do so. On page 1012 of the article he states, "We have tried to extend the monofunctional group approach used in conjugating oligosaccharides to the larger molecular size meningococcal polysaccharides. This was achieved by the introduction of a terminally located free aldehyde group into the polysaccharide molecules through which they could be specifically coupled to protein without activating the other functional groups on the poly-

saccharide. This procedure avoids cross-linking, minimizes the possibility of extraneous chemical modification of the polysaccharides, and results in better-defined immunogens."

Now, in the summary of the invention in [1816] the patent, we have wording which is very, very close to the wording in that article and contains most of the language which was obviously designed in the article to convey and elaborate upon the monofunctional approach. However, in the patent, and the language I will just read now, the word monofunctional is not there.

Thus, the patent states, and I'm reading from column 2, beginning at line 33: "We have found it possible to introduce a free aldehyde group into the polysaccharide molecule in a terminal location and to specifically couple this aldehyde group to protein without activating other functional groups on the polysaccharide. This procedure avoids cross-linking and extraneous chemical modification of the bulk of the polysaccharide resulting in better-defined immunogens."

Now, that language, in substance, and almost verbatim form, was in the article. Obviously in the article it was inexorably linked to the concept of monofunctionality. However, in the patent, although the word monofunctional was omitted, the attending language, which was an elaboration of the monofunctional idea, was carried over into the patent.

Now, anyone reading the patent will find over and over again references which talk about the single terminal group. I don't think the word single is used, but the [1817] singular usage is over and over again presented. I don't think any purpose would be served in reading all those references; but let me just set down a few of them.

The first two lines of the patent refer to a terminally located aldehyde group. That, of course, is in the singular, and as I have stated, group does not talk about linkage at two ends. It talks about a group consisting of three types of atoms. Sometimes instead of saying alde-

hyde group, we say aldehyde. It is in the singular. In column 2, line 61, there is a reference to linkage to a terminal portion. That language forecasts the language of claim 11. Column 3 refers to a terminal portion of the molecule. And of course, we come to claim 11, which has that same language, a terminal portion of the polysaccharide. There are many other references which can be easily found with the same kind of wording.

Thus, again, what happened was that the concept of the speech and article was carried over into the patent. It is true that words such as "monofunctional" were not there, but all the other attendant wording is there.

Now, the question naturally presents itself. If Dr. Jennings sought to broaden his patent beyond what was contained in the article and the speech, why did he not express this intention? If his intention was to have a patent on the production of aldehydes at both terminal ends, [1818] this is something that can be easily expressed in the English language, and clearly expressed. If he desired to depart from the objectives that he so clearly had in his experimentation described in his article and his speech, if that was his purpose, surely that was something that he thought about, it wasn't just chance, and he would want to think about how to express it.

He did not express it. And that is the basic reason why I am holding in favor of the defendants on the question of interpretation. There are ample means through simple devices of wording to convey what he claims was his intention. He simply did not do it.

My ruling is that the wording in claim 11, "a terminal portion," should be interpreted to refer to monofunctionality, and that is the way I am interpreting it.

Now, we come to the phrase "without significant cross-linking." There is some indication in plaintiffs' arguments that there was an intention along with incorporating this difunctional approach into the patent to provide for cross-linking because it has certain legitimate chemical benefits, although it does indeed have some detriments.

But there is nothing in this patent affirmatively teaching anything about achieving cross-linking. There is nothing in the patent except a negative view of [1819] cross-linking.

The proper interpretation is that the phrase "without significant cross-linking" was inserted simply to cover the possibility that I've earlier described, that in the chemical process, one cannot be assured of absolute purity, there may be some cleavage and some proteins appearing in places that were not intended, and the patent is designed to cover that situation.

This brings us to the final point about claim 11, and that is what is meant by the word "conjugate." Plaintiff contends that conjugate refers to the molecule itself. The defense contends that it refers to the mixture consisting of the various molecules which are produced. Conjugate is referred to many times in the patent. Judging from the patent as a whole, it is quite clear that conjugate in claim 11 means the mixture and not the single molecule. This is also made clear by the testimony of Dr. Jennings himself.

On the overall issue of interpretation, plaintiffs' expert witness, Dr. Schoolnik, gave very interesting testimony. He testified that if he looked at the language of the patent and the background that I've described, he would say that it only covered monofunctionality. And the only reason he could voice an opinion in favor of difunctionality —that is, covering the [1820] production of two terminal linkages at the two ends of the polysaccharide—was that there is a reference in the claims 12 and 25 and one or two references in the other portions of the patent to Haemophilus influenza. He said that the Haemophilus influenza polysaccharide, at least the one that was best known in this field of technology, would necessarily yield aldehydes at the two ends. And therefore, this reference in claim 12 and claim 25 and one or two other places drives the interpretation of the entire patent so that claim 11 covers, the whole patent covers one or both terminal

portions. It covers monofunctionality and it covers difunctionality.

I really cannot accept this proposed method of interpretation. This patent has a great deal of discussion of experimentation and theory, and it is all referring to this monofunctional approach. To allow all of that weight, really massive weight of discussion, descriptions of experiments and so forth, to be cancelled out by the two words "Haemophilus influenza," in my mind, would not be a fair method of interpretation.

Other points need to be made about claims 12 and 25. Claim 12 refers to five different groups or families of bacteria with polysaccharides. And each of those families has numerous, what are called serotypes. It has been stipulated that if the Jennings oxidation process were [1821] applied to all of these serotypes of the five groups referred to in claim 12, some would produce a monofunctional result. Some would produce a difunctional result. Some would produce a polyfunctional result; that is, protein distributed all along the polysaccharide.

And I think it is clear from the record that on some of these serotypes, it is not known what would happen. In addition, it is stipulated that on some of these serotypes which would not naturally and easily yield the monofunctional result, such a result could be obtained if there was pretreatment of the kind taught at an earlier point in the patent.

Now, as for Haemophilus influenza, this is a family or group which has five or six serotypes. Haemophilus influenza B is the one which yields the difunctional result if the Jennings type oxidation is used and if it is controlled in a way which is appropriate to Haemophilus influenza.

Plaintiffs admit that much of what is referred to in claim 12 would not be appropriate for the Jennings patent, that is, the situations where proteins are distributed all along the backbone, the polyfunctional result. Plaintiffs deal with this by saying that these situations should be read out of claim 12. They should be rejected, ignored.

[1822] The question is: What do you do with Haemophilus influenza B? In my view, the same thing should be done about Haemophilus influenza, as with the polyfunctional polysaccarides. The question should be: What is the main teaching of the patent? Does the patent, prior to claim 12, teach a difunctional result? Claim 12 and also claim 25 derive from claim 11, and obviously stem from the whole body of the descriptive material in the patent. In my view, it is improper to ignore that in respect of Haemophilus influenza any more than for the serotypes where polyfunctionality occurs. Difunctionality is simply not taught by the bulk of the descriptive material in this patent. It's not specifically taught in claim 12 or claim 25. All that we have is some alleged implication of a difunctional result resulting from the phrase Haemophilus influenza, allegedly known to scientists who know the necessary chemistry. This is far from teaching difunctionality in clear language in a patent.

There has been an argument that claims 12 and 25 are invalid because there are so many different kinds of polysaccharides referred to which would yield different results. Polyfunctional, difunctional and monofunctional, some of which results are admittedly contrary to the patent's teaching.

In other words, the contention of the defense is [1823] that claims 12 and 25 are invalid because they really don't teach anything that is definite, or define anything that is sufficiently definite in accordance with Section 112 of the patent law. I agree with that contention, and I hold that claim 12 and claim 25 are both invalid on the ground asserted by the defense. In the alternative, even if they are to be deemed valid, I hold that there is nothing in either claim which can be properly interpreted to define a difunctional result contrary to claim 11 and the teaching of the patent as a whole.

[1824] What I have ruled as far as the interpretation issues dictates the result of the infringement claim. Since the proper interpretation of the patent, including claims

12 and 25, is to define a monofunctional substance, defendants' product HibTITER cannot be held to infringe because it involves a difunctional substance.

Plaintiffs have one alternative argument about infringement which must be dealt with. They contend that even if defendants prevail on their basic interpretation arguments, still there is infringement. They contend that there is in HibTITER a certain amount of monofunctionality involved in the so-called monomers which constitute a portion of the molecules in the product.

This argument largely depends on the meaning of the word "conjugate" in claim 11. They urge that "conjugate" refers to the molecule, so a single molecule could be an infringing molecule. I reject that interpretation, as I have said, and have ruled that "conjugate" refers to the mixture.

But even as to the individual molecules, there is no showing that the HibTITER contains any truly monofunctional polysaccharides. Defendents' process creates cleavage through oxidation. The polysaccharide fragments which result have aldehydes at each of the two ends.

There are situations, apparently, where only one [1825] of those aldehydes links up to a protein, and indeed there apparently are many of those situations. But this is not because they do not have an aldehyde created at both ends. It is because, by chance, only one aldehyde links with a protein and, in a further portion of the chemical process, the other end becomes capped.

But more importantly, "conjugate" refers to a mixture, and the mixture, in order to be within claim 11, and therefore, within claims 12 and 25, must be without significant crosslinking. The evidence is overwhelming that the mixture involved in HibTITER has very substantial crosslinking.

A high proportion of the molecules are what are called dimers or trimers, and these molecules involve crosslinking to a significant degree. Therefore, there is no

infringement even on this alternative theory suggested by plaintiffs.

For the above reasons plaintiffs' complaint is dismissed.

And so that concludes our proceedings. Thank you.

MR. DIAZ: Thank you very much, your Honor.

MR. THOMASCH: One housekeeping matter, your Honor. Am I right that we should collect back our exhibits from the Court?

[1826] THE COURT: Well, I want to keep what I have on the bench.

MR. THOMASCH: All right. There's only—

THE COURT: Everything out here.

MR. THOMASCH: I think there's one confidential exhibit. We would just ask that that not be publicly filed.

THE COURT: I'll watch that.

MR. THOMASCH: Thank you, your Honor.

(Proceeding adjourned at 2:25 p.m.)

SO ORDERED.

Dated: New York, New York
September 9, 1992

/s/ Thomas P. Griesa
THOMAS P. GRIESA
U.S.D.J.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

93-1076

NORTH AMERICAN VACCINE, INC. and
NATIONAL RESEARCH COUNCIL OF CANADA,
Plaintiffs-Appellants,

v.

AMERICAN CYANAMID COMPANY and
PRAXIS BIOLOGICS, INC.,
Defendants-Appellees.

ORDER

[Filed Dec. 8, 1993]

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on December 15, 1993.

FOR THE COURT,
FRANCIS X. GINDHART
Clerk

By /s/ Diane M. Frye
DIANE M. FRYE
Chief Deputy Clerk

Dated: December 8, 1993

cc: JOHN A. DIAZ
DONALD R. DUNNER